

REMARKS

Claims 2-6, 8-13 and 15-25 are pending in the present application and all said claims stand rejected.

Applicants herein amend independent claims 6, 13 and 19 to add a limitation regarding prevention of mode switching of the cardiac sensing regime in the absence of a supra-threshold interference signal.

Applicants earnestly solicit entry and favorable consideration of the amendments and remarks presented herein.

Claim Rejections Under 35 U.S.C. §112

Claims 2-6, 20-21 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the specification as originally filed fails to disclose sensing of cardiac activity with not occur in the presence of "relatively low-energy electromagnetic interference."

Applicants herein amend the independent claims to modify the objected-to language and substitute therefor specific language from the specification as filed in support thereof. Thus, the claims now affirmatively recite that no cardiac sensing-mode switch will occur upon receipt of sub-threshold interference signals.

Claim Rejections Under 35 U.S.C. §103(a)

In the Office Action, the Examiner rejected claims 8, 9, 13, 15, and 17-25 under 35 U.S.C. §103(a) as being unpatentable over an international application to Prutchi et

al., WO 99/37360 ("Prutchi") in view of U.S. Pat. No. 6,209,764 to Hartlaub et al. ("Hartlaub").

Applicants respectfully suggest that the Prutchi and Hartlaub fail to address the unique problem addressed by the present invention; namely, detection of an interference signal characteristic of magnetic resonance imaging (MRI) interference and changing the cardiac sensing regimen when an interference signal exceeds a threshold and not changing the cardiac sensing regimen if the absence of a supra-threshold interference signal. No portion of either Prutchi or Hartlaub addresses the problem solved by the instant invention. Furthermore, neither Prutchi nor Hartlaub appear to provide any motivation, suggestion or teaching regarding an MRI-specific – and tolerant – pacing schema.

For example, an excerpt from Hartlaub reveals the "problem solved" by the invention therein; namely:

When such an external signal induces a current in the conductive loop and in turn the electrically excitable tissue, the user may experience pain and uncontrollable motor responses. Thus, this induced current is unwanted, and the present invention limits this unwanted current. (emphasis added.)

Thus, unlike the present invention, which deals only with magnetic resonance imaging ("MRI") and not the genus of electromagnetic interference ("EMI"), Hartlaub fails to contemplate a solution wherein pacing persists, albeit with an MRI-tolerant sensing (e.g., mechanical sensors in lieu of electrical sensors) scheme. To further magnify this fact, Applicants herein amend independent claims 6, 13 and 19 to eliminate the fact that the mode-switch of the present invention is not triggered by

relatively low-energy EM interference (now defined in the claims as less than about 0.17 Tesla).

That is, although abundantly clear from the specification and drawings the present invention is directed to MRI-based cardiac activity sensing. For example, neither the acronym "MRI" nor the term "Tesla" appears anywhere in Prutchi in further support for the proposition that Prutchi cannot be applied as a primary reference in any obviousness-type rejection. Accordingly, Applicant respectfully asserts that Prutchi fails to reach the required level of supporting a *prima facie* obviousness rejection. Since the Examiner has not asserted a *prima facie* obviousness rejection. The rejected claims should be allowed to pass to allowance.

Further, in contrast to Prutchi the present invention provides specifically for withholding a *sensing mode-switch* when in the presence of sub-threshold electrical fields and *affirmatively performing a sensing mode-switch* so that physiologically-based cardiac pacing and sensing can continue without pause or any ill effects on operative electrically-base sensing circuitry. Specifically, the invention is *not* directed to, or intended, to protect a subject from unpredictable electrical currents (as is the focus of Hartlaub).

As taught in the written description of the present application, the presence of MRI interference can be inferred from a signal characteristic, detected by a Hall Effect sensor, antenna or the like that strongly correlates only to the patient's proximity to an operating MRI system. To wit,

The Hall Effect sensor 500 may be capable of detecting magnetic fields having magnetic field strengths in the range of about 0.2 Tesla (2000 Gauss) to about 10 Tesla (100,000 Gauss). A magnetic field having a magnetic field strength above a threshold of about 0.17 Tesla (1700 Gauss) may be taken as an indication of the magnetic resonance imaging (MRI) scan.

Alternatively, and/or additionally, any other type of sensor capable of detecting other properties of the electromagnetic fields that may be produced during the magnetic resonance imaging (MRI) scan may be used by the detector 440 to detect the presence of the high static magnetic field. For example, other fields associated with the MRI scan, such as a static gradient magnetic field, a variable gradient magnetic field with a frequency of up to about 5 kHz, radio-frequency pulses with a frequency of up to about 50 MHz, or a variable magnetic field with a frequency of about 64 MHz, may be detected by the detector 440.

Thus, the amended claims stand amended herein to include appropriate claim elements, supported by the specification as filed, directed to detection of an operating MRI system.

Rejection of Claims 10-12 and 16

In addition, the Examiner rejected claims 10-12 and 16 under 35 U.S.C. §103(a) as being unpatentable over Prutchi in view of Hartlaub as applied above in further view of a pre-grant published application to Silvian et al.; namely, US-2002/0072769 ("Silvian"), or U.S. Pat. No. 5,882,304 to Ehnholm et al. ("Ehnholm").

Applicants herewith incorporate the above-noted deficiencies of Hartraub and further suggest that the proposed combination fails to render the claimed invention, as amended, obvious as neither reference contemplates identifying a magnetic field characteristic of an operating MRI scanning system and responding with an "MRI-safe" cardiac pacing and cardiac sensing modality. Since claim 10-12 and 16 recite the

foregoing limitations, Applicants respectfully suggest that the present ground of rejection stands traversed and should be withdrawn.

As to both obviousness-type claim rejections, Applicants assert the following. In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a prima facie case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A prima facie case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000).

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434. Determination of patentability must be based on evidence, *id.* at 1434, and the Examiner provided none: no references pertaining to aggregation or averaging were cited, no official notice was taken, no evidence of any kind was presented. The Examiner's failure to present an evidentiary basis for the decision is clearly a legal error. *Id.* Assertions such as "common knowledge and common sense," even if assumed to derive from the Examiner's expertise, are not evidence, and conclusory statements do not fulfill the

Examiner's obligation to make an evidentiary record. Id. at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. In re Lee, 61 USPQ2d at 1435 ("[W]hen they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record."). The failure to do so renders the Examiner's rejection arbitrary, capricious and unreasonable. See id. at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

The Examiner presented no evidence of any suggestion or motivation to modify the prior art to arrive at the claimed invention. Nor has the Examiner presented any evidence that the recited elements are known in the art. The record consists exclusively of conclusory statements by the Examiner, which are not evidence and which cannot support rejections under 35 U.S.C. § 103.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicants' pending claims under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested.

CONCLUSION

Applicant respectfully asserts that all presently pending claims in the application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims so that the claimed invention may pass to timely issuance as U.S. Letters Patent.

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Art Unit: 3737

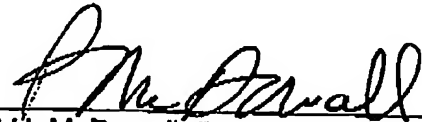
Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

Date:

6 June 05

By:



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